K131488

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hkatz@AlfaWassermannUS.com Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	AUG 19 2013
Date Summary Prepared:	July 12, 2013	
Device:	Trade Name:	ACE Albumin Reagent
	Classification:	Class 2
	Common/Classification Name:	Bromcresol Green Dye-Binding, Albumin (21 C.F.R. § 862.1035) Product Code CIX
	Trade Name:	ACE Total Protein Reagent
	Classification:	Class 2
	Common/Classification Name:	Biuret (Colorimetric), Total Protein (21 C.F.R. § 862.1635) Product Code CEK
	Trade Name:	ACE Calcium-Arsenazo Reagent
	Classification:	Class 2
	Common/Classification Name:	Azo Dye, Calcium (21 C.F.R. § 862.1445) Product Code CJY
	Trade Name:	ACE Inorganic Phosphorus U.V. Reagent
	Classification:	Class 1
	Common/Classification Name:	Phosphomolybdate (Colorimetric), Inorganic Phosphorus (21 C.F.R. § 862.1580) Product Code CEO
Predicate Devices:	Manufacturer for reagent system predicates: Alfa Wassermann ACE and ACE Axcel Clinical Chemistry Systems and ACE Reagents (K930104, K113253, K113374)	

Device Descriptions:	In the ACE Albumin Reagent assay, Bromcresol green binds specifically to albumin to form a green colored complex, which is measured bichromatically at 629 nm/692 nm. The intensity of color produced is directly proportional to the albumin concentration in the sample. In the ACE Total Protein Reagent assay, cupric ions react with the peptide bonds of proteins under alkaline conditions to form a violet colored complex, which is measured bichromatically at 544 nm/692 nm. The intensity of color produced is directly proportional to the total protein concentration in the sample. In the ACE Calcium-Arsenazo Reagent assay, calcium reacts with Arsenazo III in an acidic solution to form a blue-purple colored complex, which is measured bichromatically at 647 nm/692 nm. The intensity of color produced is directly proportional to the calcium concentration in the sample. In the ACE Inorganic Phosphorus U.V. Reagent assay, under acidic conditions, inorganic phosphorus in serum reacts with ammonium molybdate to form an unreduced phosphomolybdate complex, which absorbs strongly at 340 nm. The increase in absorbance, measured bichromatically at 340 nm/378 nm, is directly proportional to the amount of phosphorus in the sample.
Intended Use:	Indications for Use: ACE Albumin Reagent is intended for the quantitative determination of albumin concentration in serum and lithium heparin plasma using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. ACE Total Protein Reagent is intended for the quantitative determination of total protein concentration in serum and lithium heparin plasma using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. Total protein measurements are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only. ACE Calcium-Arsenazo Reagent is intended for the quantitative determination of calcium concentration in serum and lithium heparin plasma using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms). This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

	ACE Inorganic Phosphorus U.V. Reagent is intended for the quantitative determination of inorganic phosphorus concentration in serum and lithium heparin plasma using the ACE, ACE Alera, and ACE Axcel Clinical Chemistry Systems. Measurements of inorganic phosphorus are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases and vitamin D imbalance. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.
Technological Characteristics:	ACE Albumin Reagent consists of a single reagent bottle. The reagent contains Bromcresol green and acetate buffer. ACE Total Protein Reagent consists of a single reagent bottle. The reagent contains copper sulfate, sodium potassium tartrate, potassium iodide and sodium hydroxide. ACE Calcium-Arsenazo Reagent consists of a single reagent bottle. The Reagent contains Arsenazo III. ACE Inorganic Phosphorus U.V. Reagent consists of a single reagent bottle. The reagent contains ammonium molybdate and sulfuric acid.

Device Comparison with Predicate

Comparison of similarities and differences with predicate device

ACE Albumin Reagent

ALB	Candidate Device	Predicate Device K930104 (ACE ALB)
Intended Use/ Indications for Use	The ACE Albumin Reagent is intended for the quantitative determination of albumin concentration .	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	30 days	Same
On-Board Stability	30 Days	Same
Sample Type	Serum and lithium heparin plasma	Serum
Sample Volume	3 µL	Same
Reaction Volume	463 µL	Same
Expected Values	3.5 – 5.2 g/dL	Same
Measuring Range	0.1 – 7.6 g/dL	Same
Sample Stability	Specimen stable at 4°C for up to 72 hours and frozen at -20°C for 6 months or indefinitely at -70°C.	Same

ACE Total Protein Reagent

Total Protein	Candidate Device	Predicate Device K930104 (ACE Total Protein)
Intended Use/ Indications for Use	The ACE Total Protein Reagent is intended for the quantitative determination of total protein concentration.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	30 Days	Same
On-Board Stability	30 Days	Same
Sample Type	Serum and lithium heparin plasma	Serum
Sample Volume	3 µL	Same
Reaction Volume	218 µL	Same
Expected Values	6.0 – 8.3 g/dL	Same
Measuring Range	0.2 – 15.1 g/dL	Same
Sample Stability	Specimen stable at 4°C for up to 72 hours and frozen at -20°C for 6 months or indefinitely at -70°C.	Same

Device Comparison with Predicate

ACE Calcium-Arsenazo Reagent

Calcium-Arsenazo	Candidate Device	Predicate Device K930104 (ACE Calcium-Arsenazo)
Intended Use/ Indications for Use	ACE Calcium-Arsenazo Reagent is intended for the quantitative determination of calcium.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	30 Days	Same
On-Board Stability	30 Days	Same
Sample Type	Serum and lithium heparin plasma	Serum
Sample Volume	3 µL	Same
Reaction Volume	318 µL	Same
Expected Values	8.5 – 10.2 mg/dL	Same
Measuring Range	0.2 – 16.5 mg/dL	Same
Sample Stability	Specimen stable for 7 days at 20-25°C, 3 weeks at 4-8°C, and 8 months at -20°C	Same

ACE Inorganic Phosphorus U.V. Reagent

Inorganic Phosphorus	Candidate Device	Predicate Device K930104 (ACE Inorganic Phosphorus)
Intended Use/ Indications for Use	ACE Inorganic Phosphorus U.V. Reagent is intended for the quantitative determination of inorganic phosphorus.	Same
Platforms	ACE, ACE *Alera*®, and ACE Axcel Clinical Chemistry Systems	ACE Clinical Chemistry System
Method	Photometric	Same
Calibration Stability	30 Days	Same
On-Board Stability	30 Days	Same
Sample Type	Serum and lithium heparin plasma	Serum
Sample Volume	3 µL	Same
Reaction Volume	218 µL	Same
Expected Values	2.7 - 4.5 mg/dL	Same
Measuring Range	0.4 – 21 mg/dL	Same
Sample Stability	Specimen stable for 4 days at 4-8°C and for 1 year at -20°C.	Same

Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE, ACE *Alera* and ACE Axcel Clinical Chemistry Systems

In-House Precision: Serum vs. Plasma – ACE Albumin Reagent

		Precision (SD, %CV)							
Albumin g/dL	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**	**Axcel Mean**	**Within-Run**	**Total**
Serum Low	4.1	0.05, 1.3%	0.07, 1.6%	4.1	0.04, 0.9%	0.04, 1.1%	4.1	0.02, 0.5%	0.04, 1.0%
Plasma Low	3.8	0.06, 1.7%	0.06, 1.7%	3.7	0.03, 0.8%	0.05, 1.4%	3.7	0.06, 1.6%	0.06, 1.6%
Serum Mid	5.4	0.08, 1.6%	0.10, 1.8%	5.3	0.05, 1.0%	0.06, 1.1%	5.3	0.03, 0.6%	0.03, 0.6%
Plasma Mid	5.0	0.05, 1.0%	0.07, 1.4%	5.0	0.08, 1.7%	0.08, 1.7%	4.9	0.04, 0.9%	0.05, 1.1%
Serum High	6.5	0.07, 1.1%	0.11, 1.6%	6.5	0.05, 0.8%	0.08, 1.3%	6.4	0.06, 1.0%	0.09, 1.3%
Plasma High	6.2	0.09, 1.5%	0.10, 1.7%	6.1	0.08, 1.3%	0.10, 1.6%	6.1	0.05, 0.9%	0.08, 1.3%

In-House Precision: Serum vs. Plasma – ACE Total Protein Reagent

		Precision (SD, %CV)							
Total Protein g/dL	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**	**Axcel Mean**	**Within-Run**	**Total**
Serum Low	6.7	0.06, 1.0%	0.07, 1.0%	6.7	0.05, 0.7%	0.05, 0.8%	6.8	0.08, 1.1%	0.09, 1.3%
Plasma Low	7.2	0.06, 0.9%	0.06, 0.9%	7.1	0.08, 1.1%	0.09, 1.2%	7.2	0.05, 0.8%	0.07, 0.9%
Serum Mid	8.4	0.11, 1.3%	0.11, 1.3%	8.4	0.08, 1.0%	0.08, 1.0%	8.4	0.07, 0.8%	0.11, 1.4%
Plasma Mid	8.8	0.04, 0.5%	0.06, 0.7%	8.7	0.06, 0.7%	0.1, 1.2%	8.8	0.07, 0.8%	0.08, 0.9%
Serum High	10.1	0.07, 0.7%	0.08, 0.8%	10.0	0.07, 0.7%	0.09, 0.9%	10.1	0.07, 0.7%	0.09, 0.9%
Plasma High	10.3	0.13, 1.3%	0.14, 1.4%	10.2	0.11, 1.1%	0.14, 1.3%	10.4	0.08, 0.8%	0.10, 1.0%

In-House Precision: Serum vs. Plasma – ACE Calcium-Arsenazo Reagent

		Precision (SD, %CV)							
Calcium-Arsenazo mg/dL	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**	**Axcel Mean**	**Within-Run**	**Total**
Serum Low	9.3	0.12, 1.3%	0.25, 2.7%	9.3	0.09, 0.9%	0.22, 2.4%	9.3	0.08, 0.8%	0.17, 1.8%
Plasma Low	8.4	0.04, 0.5%	0.2, 2.4%	8.3	0.10, 1.2%	0.17, 2.0%	8.3	0.08, 0.9%	0.11, 1.4%
Serum Mid	11.7	0.18, 1.6%	0.2, 1.7%	11.6	0.14, 1.2%	0.14, 1.2%	11.6	0.1, 0.9%	0.11, 0.9%
Plasma Mid	10.7	0.19, 1.7%	0.20, 1.9%	10.7	0.13, 1.2%	0.15, 1.4%	10.7	0.12, 1.2%	0.13, 1.2%
Serum High	13.9	0.20, 1.4%	0.2, 1.4%	13.8	0.19, 1.4%	0.19, 1.4%	13.8	0.09, 0.7%	0.11, 0.8%
Plasma High	13.0	0.25, 1.9%	0.26, 2.0%	12.9	0.13, 1.0%	0.14, 1.1%	13.1	0.15, 1.2%	0.18, 1.4%

In-House Precision: Serum vs. Plasma – ACE Inorganic Phosphorus Reagent

	Precision (SD, %CV)								
Inorganic Phosphorus U.V. mg/dL	**ACE Mean**	**Within-Run**	**Total**	**Alera Mean**	**Within-Run**	**Total**	**Axcel Mean**	**Within-Run**	**Total**
Serum Low	3.5	0.15, 4.4%	0.17, 5.0%	3.4	0.11, 3.1%	0.14, 4.0%	3.5	0.11, 3.1%	0.14, 4.1%
Plasma Low	3.1	0.16, 5.1%	0.18, 5.9%	3.0	0.11, 3.7%	0.15, 5.0%	3.1	0.15, 5.0%	0.19, 6.1%
Serum Mid	10.2	0.04, 0.3%	0.05, 0.5%	9.9	0.08, 0.8%	0.08, 0.8%	10.2	0.04, 0.4%	0.12, 1.2%
Plasma Mid	9.8	0.09, 0.9%	0.09, 0.9%	9.6	0.07, 0.8%	0.08, 0.8%	9.9	0.06, 0.6%	0.12, 1.2%
Serum High	17.0	0.26, 1.5%	0.26, 1.6%	16.6	0.22, 1.3%	0.22, 1.3%	17.3	0.28, 1.6%	0.30, 1.7%
Plasma High	16.7	0.23, 1.4%	0.24, 1.4%	16.3	0.24, 1.5%	0.29, 1.8%	16.9	0.30, 1.8%	0.32, 1.9%

Performance Data:

In-House Precision – Serum vs. Plasma

Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE, ACE *Alera* and ACE Axcel Clinical Chemistry Systems

In-House Matrix Comparison: Serum vs. Plasma – ACE Albumin Reagent

System	Range	Results - Serum vs. Plasma	
ACE	0.3-6.8 g/dL	Slope:	0.991
		Intercept:	0.03
55 pairs		Correlation:	0.9874
		Std. Error Est:	0.19
		Confidence Interval Slope:	0.948 to 1.034
		Confidence Interval Intercept:	-0.15 to 0.20
ACE *Alera*	0.3-6.8 g/dL	Slope:	1.002
		Intercept:	-0.01
56 pairs		Correlation:	0.9905
		Std. Error Est:	0.17
		Confidence Interval Slope:	0.964 to 1.040
		Confidence Interval Intercept:	-0.15 to 0.14
ACE Axcel	0.7-6.7 g/dL	Slope:	0.956
		Intercept:	0.20
56 pairs		Correlation:	0.9850
		Std. Error Est:	0.20
		Confidence Interval Slope:	0.911 to 1.001
		Confidence Interval Intercept:	0.04 to 0.37

In-House Matrix Comparison: Serum vs. Plasma – ACE Total Protein Reagent

System	Range	Results - Serum vs. Plasma	
ACE	0.5-12.3 g/dL	Slope:	1.001
		Intercept:	0.12
56 pairs		Correlation:	0.9798
		Std. Error Est:	0.40
		Confidence Interval Slope:	0.946 to 1.056
		Confidence Interval Intercept:	-0.24 to 0.48
ACE *Alera*	0.5-12.0 g/dL	Slope:	0.999
		Intercept:	0.14
56 pairs		Correlation:	0.9840
		Std. Error Est:	0.35
		Confidence Interval Slope:	0.950 to 1.047
		Confidence Interval Intercept:	-0.18 to 0.46
ACE Axcel	0.5-13.9 g/dL	Slope:	0.994
		Intercept:	0.34
81 pairs		Correlation:	0.9885
		Std. Error Est:	0.26
		Confidence Interval Slope:	0.961 to 1.028
		Confidence Interval Intercept:	0.12 to 0.57

Performance Data:

In-House Precision – Serum vs. Plasma

In-House Matrix Comparison: Serum vs. Plasma – ACE Calcium-Aresnazo Reagent

System	Range	Results - Serum vs. Plasma	
ACE	1.0-13.7 mg/dL	Slope:	1.006
		Intercept:	-0.01
56 pairs		Correlation:	0.9824
		Std. Error Est:	0.39
		Confidence Interval Slope:	0.955 to 1.058
		Confidence Interval Intercept:	-0.46 to 0.45
ACE *Alera*	1.0-13.7 mg/dL	Slope:	1.008
		Intercept:	-0.06
56 pairs		Correlation:	0.9793
		Std. Error Est:	0.43
		Confidence Interval Slope:	0.952 to 1.064
		Confidence Interval Intercept:	-0.55 to 0.42
ACE Axcel	0.7-15.0 mg/dL	Slope:	0.978
		Intercept:	0.33
81 pairs		Correlation:	0.9911
		Std. Error Est:	0.23
		Confidence Interval Slope:	0.949 to 1.007
		Confidence Interval Intercept:	0.06 to 0.60

In-House Matrix Comparison: Serum vs. Plasma – ACE Inorganic Phosphorus Reagent

System	Range	Results - Serum vs. Plasma	
ACE	1.3-19.3 mg/dL	Slope:	1.042
		Intercept:	-0.26
100 pairs		Correlation:	0.9927
		Std. Error Est:	0.33
		Confidence Interval Slope:	1.017 to 1.067
		Confidence Interval Intercept:	-0.38 to -0.14
ACE *Alera*	1.3-19.3 mg/dL	Slope:	1.049
		Intercept:	-0.28
102 pairs		Correlation:	0.9928
		Std. Error Est:	0.33
		Confidence Interval Slope:	1.024 to 1.074
		Confidence Interval Intercept:	-0.40 to -0.16
ACE Axcel	0.5-19.8 mg/dL	Slope:	0.999
		Intercept:	0.04
56 pairs		Correlation:	0.9950
		Std. Error Est:	0.34
		Confidence Interval Slope:	0.972 to 1.027
		Confidence Interval Intercept:	-012 to 0.20

Performance Data:

In-House Matrix Comparison – Serum vs. Plasma

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

(Note: Refer to previously cleared submission k113374 for ACE Axcel POL data)

Albumin			**ACE Result** g/dL SD, %CV			**ACE Alera Result** g/dL SD, %CV	
Lab	Sample	Mean	Within-Run	Total	Mean	Within-Run	Total
In-House	1	3.5	0.05	0.07	3.5	0.02	0.04
			1.4%	2.0%		0.6%	1.1%
POL 1	1	3.5	0.04	0.04	3.5	0.05	0.06
			1.3%	1.3%		1.4%	1.7%
POL 2	1	3.5	0.06	0.07	3.6	0.05	0.05
			1.7%	2.0%		1.4%	1.5%
POL 3	1	3.5	0.08	0.08	3.5	0.05	0.05
			2.3%	2.4%		1.6%	1.6%
In-House	2	5.0	0.06	0.06	5.0	0.05	0.05
			1.2%	1.2%		1.0%	1.1%
POL 1	2	4.9	0.06	0.07	5.0	0.08	0.09
			1.2%	1.4%		1.7%	1.9%
POL 2	2	4.9	0.03	0.06	5.0	0.06	0.08
			0.6%	1.2%		1.2%	1.6%
POL 3	2	4.9	0.06	0.09	4.9	0.03	0.03
			1.2%	1.9%		0.6%	0.7%
In-House	3	6.2	0.11	0.13	6.2	0.06	0.07
			1.9%	2.1%		1.0%	1.1%
POL 1	3	6.1	0.07	0.07	6.2	0.07	0.10
			1.1%	1.2%		1.1%	1.6%
POL 2	3	6.1	0.10	0.12	6.2	0.06	0.07
			1.6%	1.9%		1.0%	1.1%
POL 3	3	6.1	0.10	0.11	6.1	0.08	0.08
			1.7%	1.8%		1.3%	1.4%

Performance Data:

In-House Matrix Comparison – Serum vs. Plasma

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

Total Protein			ACE Result g/dL SD, %CV			ACE Alera Result g/dL SD, %CV	
Lab	Sample	Mean	Within-Run	Total	Mean	Within-Run	Total
In-House	1	5.3	0.05	0.06	5.3	0.08	0.10
			0.9%	1.2%		1.5%	1.8%
POL 1	1	5.3	0.13	0.13	5.5	0.07	0.10
			2.5%	2.5%		1.4%	1.8%
POL 2	1	5.3	0.08	0.16	5.2	0.07	0.15
			1.5%	3.1%		1.3%	2.8%
POL 3	1	5.6	0.10	0.12	5.6	0.07	0.12
			1.7%	2.1%		1.4%	2.2%
In-House	2	8.3	0.10	0.12	8.3	0.10	0.11
			1.2%	1.4%		1.2%	1.4%
POL 1	2	8.2	0.08	0.11	8.4	0.09	0.10
			1.0%	1.4%		1.1%	1.2%
POL 2	2	8.3	0.06	0.18	8.4	0.10	0.11
			0.7%	2.1%		1.2%	1.4%
POL 3	2	8.6	0.04	0.10	8.2	0.09	0.14
			0.5%	1.1%		1.1%	1.7%
In-House	3	11.2	0.14	0.17	11.3	0.14	0.15
			1.3%	1.5%		1.3%	1.4%
POL 1	3	11.2	0.14	0.17	11.3	0.14	0.14
			1.3%	1.5%		1.2%	1.2%
POL 2	3	11.2	0.09	0.20	11.5	0.09	0.16
			0.8%	1.8%		0.8%	1.4%
POL 3	3	11.4	0.22	0.23	11.1	0.26	0.31
			1.9%	2.0%		2.3%	2.8%

Performance Data:

Precision - POL

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

Calcium-Arsenazo			ACE Result mg/dL SD, %CV			ACE Alera Result mg/dL SD, %CV	
Lab	Sample	Mean	Within-Run	Total	Mean	Within-Run	Total
In-House	1	7.0	0.12 SD	0.17 SD	6.9	0.08 SD	0.15 SD
			1.7	2.4		1.2%	2.1%
POL 1	1	7.0	0.14 SD	0.15 SD	6.9	0.07 SD	0.19 SD
			2.0%	2.1%		1.0%	2.7%
POL 2	1	7.0	0.16 SD	0.17 SD	7.0	0.19 SD	0.19 SD
			2.3%	2.4%		2.7%	2.7%
POL 3	1	7.0	0.16 SD	0.17 SD	7.0	0.14 SD	0.14 SD
			2.3%	2.4%		1.9%	1.9%
In-House	2	10.7	0.21 SD	0.21 SD	10.5	0.05 SD	0.06 SD
			2.0%	2.0%		0.5%	0.6%
POL 1	2	10.6	0.06 SD	0.06 SD	10.5	0.09 SD	0.33 SD
			0.6%	0.6%		0.9%	3.2%
POL 2	2	10.5	0.12 SD	0.15 SD	10.6	0.21 SD	0.22 SD
			1.2%	1.5%		1.9%	2.1%
POL 3	2	10.5	0.10 SD	0.11 SD	10.6	0.16 SD	0.16 SD
			1.0%	1.0%		1.5%	1.5%
In-House	3	13.6	0.11 SD	0.26 SD	13.5	0.17 SD	0.20 SD
			0.8%	1.9%		1.3%	1.5%
POL 1	3	13.6	0.14 SD	0.20 SD	13.4	0.14 SD	0.34 SD
			1.1%	1.5%		1.1%	2.5%
POL 2	3	13.5	0.32 SD	0.37 SD	13.6	0.21 SD	0.23 SD
			2.3%	2.7%		1.5%	1.7%
POL 3	3	13.6	0.16 SD	0.17 SD	13.6	0.14 SD	0.18 SD
			1.2%	1.2%		1.0%	1.3%

Performance Data:

Precision - POL

POL – Precision for ACE and ACE *Alera* Clinical Chemistry Systems

Inorganic Phosphorus U.V.			ACE Result mg/dL SD, %CV			ACE Alera Result mg/dL SD, %CV	
Lab	Sample	Mean	Within-Run	Total	Mean	Within-Run	Total
In-House	1	2.7	0.08 SD	0.08 SD	2.8	0.06 SD	0.06 SD
			3.0%	3.0%		2.1%	2.1%
POL 1	1	2.7	0.03 SD	0.05 SD	2.7	0.04 SD	0.10 SD
			1.2%	1.9%		1.4%	3.8%
POL 2	1	2.6	0.06 SD	0.09 SD	2.5	0.02 SD	0.11 SD
			2.3%	3.6%		0.9%	4.4%
POL 3	1	2.8	0.06 SD	0.10 SD	2.9	0.05 SD	0.07 SD
			2.1%	3.5%		1.9%	2.4%
In-House	2	7.0	0.07 SD	0.09 SD	7.1	0.07 SD	0.09 SD
			1.0%	1.3%		0.9%	1.3%
POL 1	2	7.0	0.04 SD	0.07 SD	7.1	0.07 SD	0.18 SD
			0.6%	1.1%		0.9%	2.5%
POL 2	2	6.7	0.08 SD	0.14 SD	6.7	0.07 SD	0.22 SD
			1.2%	2.1%		1.1%	3.2%
POL 3	2	7.2	0.04 SD	0.07 SD	7.4	0.10 SD	0.13 SD
			0.6%	1.0%		1.4%	1.7%
In-House	3	11.1	0.14 SD	0.18 SD	11.3	0.09 SD	0.11 SD
			1.2%	1.6%		0.8%	0.9%
POL 1	3	11.1	0.13 SD	0.14 SD	11.3	0.16 SD	0.27 SD
			1.2%	1.3%		1.4%	2.4%
POL 2	3	10.9	0.12 SD	0.21 SD	10.6	0.15 SD	0.21 SD
			1.1%	1.9%		1.4%	1.9%
POL 3	3	11.4	0.13 SD	0.18 SD	11.7	0.11 SD	0.14 SD
			1.1%	1.6%		0.9%	1.2%

Performance Data:

Precision - POL

POL – Method Comparison for ACE Clinical Chemistry System

Reagent	Statistic	ACE In-House (x) vs. ACE POL 1 (y)	ACE In-House (x) vs. ACE POL 2 (y)	ACE In-House (x) vs. ACE POL 3 (y)
Albumin	n	50	50	50
	Range (g/dL)	1.0 to 6.4	1.0 to 6.4	1.0 to 6.4
	Regression	y = 0.983x + 0.03	y = 0.992x – 0.01	y = 1.006x – 0.03
	Correlation	0.9934	0.9965	0.9971
	Std. Error Est.	0.10	0.08	0.07
	CI Slope	0.950 to 1.016	0.968 to 1.016	0.984 to 1.028
	CI Intercept	-0.11 to 0.17	-0.11 to 0.09	-0.12 to 0.06
Total Protein	n	51	51	51
	Range (g/dL)	0.9 to 13.6	0.9 to 13.6	0.9 to 13.6
	Regression	y = 1.008x + 0.02	y = 1.007x + 0.06	y = 1.029x + 0.01
	Correlation	0.9957	0.9976	0.9960
	Std. Error Est.	0.15	0.11	0.15
	CI Slope	0.981 to 1.035	0.987 to 1.027	1.003 to 1.056
	CI Intercept	-0.17 to 0.22	-0.08 to 0.20	-0.18 to 0.20
Calcium-Arsenazo	n	50	50	50
	Range (mg/dL)	1.9 to 13.7	1.9 to 13.7	1.9 to 13.7
	Regression	y = 1.004x - 0.07	y = 1.002x – 0.17	y = 0.981x + 0.09
	Correlation Std.	0.9915	0.9944	0.9951
	Error Est. CI	0.26	0.21	0.19
	Slope	0.966 to 1.042	0.971 to 1.033	0.953 to 1.009
	CI Intercept	-0.42 to 0.27	-0.45 to 0.11	-0.17 to 0.34
Inorganic Phosphorus U.V.	n	50	48	50
	Range (mg/dL)	1.0 to 18.4	1.0 to 18.4	1.0 to 18.4
	Regression	y = 0.966x + 0.13	y = 1.007x – 0.10	y = 0.975x + 0.11
	Correlation Std.	0.9991	0.9982	0.9987
	Error Est. CI	0.12	0.16	0.14
	Slope	0.954 to 0.978	0.989 to 1.025	0.960 to 0.989
	CI Intercept	0.07 to 0.19	-0.18 to -0.01	0.04 to 0.19

Performance Data:

Precision - POL

POL – Method Comparison for ACE Alera Clinical Chemistry System

Reagent	Statistic	ACE In-House (x) vs. ACE Alera POL 1 (y)	ACE In-House (x) vs. ACE Alera POL 2 (y)	ACE In-House (x) vs. ACE Alera POL 3 (y)
Albumin	n	50	50	50
	Range (g/dL)	1.0 to 6.4	1.0 to 6.4	1.0 to 6.4
	Regression	y = 1.004x – 0.03	y = 1.005x – 0.05	y = 0.982x + 0.01
	Correlation	0.9949	0.9960	0.9967
	Std. Error Est.	0.09	0.08	0.07
	CI Slope	0.975 to 1.034	0.979 to 1.031	0.959 to 1.005
	CI Intercept	-0.15 to 0.10	-0.16 to 0.06	-0.09 to 0.11
Total Protein	n	51	51	51
	Range (g/dL)	0.9 to 13.6	0.9 to 13.6	0.9 to 13.6
	Regression	y = 0.998x + 0.16	y = 1.027x – 0.06	y = 0.979x + 0.24
	Correlation	0.9969	0.9962	0.9964
	Std. Error Est.	0.13	0.14	0.14
	CI Slope	0.976 to 1.020	1.002 to 1.053	0.955 to 1.003
	CI Intercept	0.00 to 0.33	-0.24 to 0.13	0.07 to 0.42
Calcium-Arsenazo	n	50	50	50
	Range (mg/dL)	1.9 to 13.7	1.9 to 13.7	1.9 to 13.7
	Regression	y = 0.992x – 0.09	y = 1.007x – 0.11	y = 1.008x – 0.08
	Correlation Std.	0.9904	0.9929	0.9929
	Error Est. CI	0.27	0.23	0.23
	Slope	0.952 to 1.032	0.972 to 1.042	0.973 to 1.043
	CI Intercept	-0.46 to 0.27	-0.43 to 0.21	-0.40 to 0.23
Inorganic Phosphorus U.V.	n	50	50	50
	Range (mg/dL)	1.0 to 18.4	1.0 to 18.4	1.0 to 18.4
	Regression	y = 1.015x + 0.14	y = 0.960x + 0.12	y = 0.984x + 0.05
	Correlation Std.	0.9992	0.9986	0.9991
	Error Est. CI	0.12	0.14	0.12
	Slope	1.003 to 1.027	0.945 to 0.974	0.972 to 0.996
	CI Intercept	0.08 to 0.20	0.05 to 0.19	-0.01 to 0.11

Performance Data:

Method Comparison - POL on ACE

Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE *Alera* Clinical Chemistry Systems

Detection Limits - ACE *Alera* Clinical Chemistry System

ACE Alera	ALB (g/dL)	TP (g/dL)	CA (mg/dL)	PHOS (mg/dL)
LoB	0.08	0.08	0.09	0.25
LoD	0.09	0.13	0.11	0.35
LoQ	0.09	0.20	0.23	0.35

Linearity - ACE *Alera* Clinical Chemistry System

ACE Reagents	Low Level Tested	Upper Level Tested	Linear to:	Linear Regression Equation
ALB	0.1 g/dL	7.6 g/dL	7.6 g/dL	$y = 0.980x + 0.01$ $r^2 = 0.9982$
TP	0.2 g/dL	15.1 g/dL	15.1 g/dL	$y = 0.991x + 0.04$ $r^2 = 0.9979$
CA	0.3 g/dL	16.5 mg/dL	16.5 mg/dL	$y = 0.992x + 0.27$ $r^2 = 0.9990$
PHOS	0.2 mg/dL	21 mg/dL	21 mg/dL	$y = 1.001x + 0.03$ $r^2 = 0.9995$

Performance Data:

ACE *Alera*

Interferences - ACE *Alera* Clinical Chemistry System

Interferents on ACE *Alera*	No Significant Interference at or below:			
	ALB	**TP**	**CA**	**PHOS**
Icterus	60 mg/dL	56.8 mg/dL	58.8 mg/dL	11.5 mg/dL
Hemolysis	250 mg/dL	250 mg/dL	1000 mg/dL	250 mg/dL
Lipemia	1000 mg/dL	929 mg/dL	1000 mg/dL	306 mg/dL
Ascorbic Acid	6 mg/dL	6 mg/dL	6 mg/dL	6 mg/dL

Precision - ACE *Alera* Clinical Chemistry System

~~on~~ ACE *Alera*		*Precision (SD, %CV)*		
		Mean	**Within-Run**	**Total**
ALB g/dL	Serum Low	2.6	0.03, 1.3%	0.05, 2.0%
	Serum Mid	3.4	0.07, 1.9%	0.09, 2.5%
	Serum High	4.3	0.03, 0.7%	0.10, 2.3%
CA mg/dL	Serum Low	6.5	0.08, 1.3%	0.13, 2.1%
	Serum Mid	9.8	0.12, 1.2%	0.22, 2.3%
	Serum High	12.6	0.23, 1.8%	0.29, 2.3%
TP g/dL	Serum Low	4.2	0.10, 2.3%	0.11, 2.6%
	Serum Mid	6.8	0.09, 1.3%	0.14, 2.1%
	Serum High	10.1	0.23, 2.3%	0.32, 3.1%
PHOS mg/dL	Serum Low	2.0	0.04, 2.3%	0.11, 5.7%
	Serum Mid	3.8	0.12, 3.2%	0.16, 4.2%
	Serum High	6.5	0.17, 2.5%	0.24, 3.6%

Performance Data:

ACE *Alera*

Method Comparison - ACE *Alera* Clinical Chemistry System

In-House ACE (x) versus In-House ACE Alera (y)				
	ALB	**TP**	**CA**	**PHOS**
n	50	56	55	55
Range	1.0 - 6.4 g/dL	0.2 - 13.6 g/dL	0.2 - 13.7 mg/dL	0.2 -18.4 mg/dL
Slope	1.005	1.009	0.991	1.006
Intercept	-0.03	-0.01	-0.02	-0.01
Correlation Coefficient	0.9961	0.9988	0.9990	0.9994
Std. Error	0.08	0.12	0.13	0.10
CI Slope	0.979 to 1.030	0.995 to 1.022	0.979 to 1.003	0.997 to 1.016
CI Intercept	-0.13 to 0.08	-0.10 to 0.08	-0.13 to 0.08	-0.06 to 0.03

Conclusions:

Based on the foregoing data, the device is safe and effective for use in clinical laboratories and physician office laboratories. This data indicates substantial equivalence for lithium heparin plasma sample collection tubes to the predicate device's use of serum sample collection tubes. This data also indicates that the ACE *Alera* Clinical Chemistry System is substantially equivalent to the predicate device ACE Clinical Chemistry System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 19, 2013

Alfa Wassermann Diagnostic Technologies, LLC
C/O Hyman Katz, Ph.D.
4 Henderson Drive
WEST CALDWELL NJ 07006

Re: K131488
Trade/Device Name: ACE Albumin Reagent
ACE Total Protein Reagent
ACE Calcium-Arsenazo Reagent
ACE Inorganic Phosphorus U.V. Reagent
Regulation Number: 21 CFR 862.1035
Regulation Name: Albumin test system
Regulatory Class: II
Product Code: CIX, CEK, CJY, CEO
Dated: July 17, 2013
Received: July 18, 2013

Dear Dr. Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k131488

Device Name: ACE Albumin Reagent

Indications for Use: ACE Albumin Reagent is intended for the quantitative determination of albumin concentration in **serum and lithium heparin plasma** using the ACE, ACE Alera and ACE Axcel Clinical Chemistry Systems. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Device Name: ACE Total Protein Reagent

Indications for Use: ACE Total Protein Reagent is intended for the quantitative determination of total protein concentration in **serum and lithium heparin plasma** using the ACE, ACE Alera and ACE Axcel Clinical Chemistry Systems. Total protein measurements are used in the diagnosis and treatment of a variety of diseases involving the liver, kidney, or bone marrow as well as other metabolic or nutritional disorders. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE: CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices or Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off
Office of In Vitro Devices or Radiological Health
510(k) k131488

Indications for Use

510(k) Number (if known): k131488

Device Name: ACE Calcium-Arsenazo Reagent

Indications for Use: ACE Calcium-Arsenazo Reagent is intended for the quantitative determination of calcium concentration in **serum and lithium heparin plasma** using the ACE, ACE Alera and ACE Axcel Clinical Chemistry Systems. Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms). This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Device Name: ACE Inorganic Phosphorus U.V. Reagent

Indications for Use: ACE Inorganic Phosphorus U.V. Reagent is intended for the quantitative determination of inorganic phosphorus concentration in **serum and lithium heparin plasma** using the ACE, ACE Alera and ACE Axcel Clinical Chemistry Systems. Measurements of inorganic phosphorus are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases and vitamin D imbalance. This test is intended for use in clinical laboratories or physician office laboratories. For *in vitro* diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

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